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FSN MA-FCO 72800616

2016-Apr

## **URGENT - Field Safety Notice**

### ***PHILIPS MX 16-slice Computed tomography x-ray system***

***Software upgrade from v1.1.4.21425 to v1.1.4.21428 to correct software issues on v1.1.4.21425***

Dear Customer,

As part of Philips' continuous focus on reliability and safety we continuously monitor the performance of our products. During recent evaluations of the Philips *MX-16 Slice*, we have identified a potential issue that may affect the performance of the equipment under certain conditions. This letter is intended to provide you with information regarding:

- what the issue is, and under what circumstances it may occur
- the actions you can take to avoid or minimize the occurrence of the issue
- the actions planned by Philips to correct the issue

**This document contains important information for the continued safe and proper use of your equipment**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain a copy with the equipment Instruction for Use.

If you need any further information or support concerning this, please contact your local Philips representative:

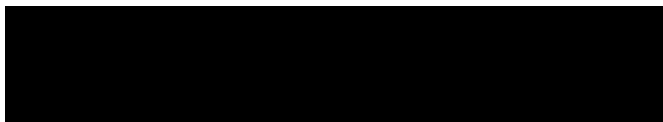
<Philips representative contact details to be completed by the KM / country>

We apologize for any inconvenience this may cause and trust that this information is adequately addressing any concerns you may have.

Sincerely,

<Signature, to be signed by Senior Management of the BS/BU/BL or GS&S/KM>

Alina Zhou  
Site Q&R Leader, IS China



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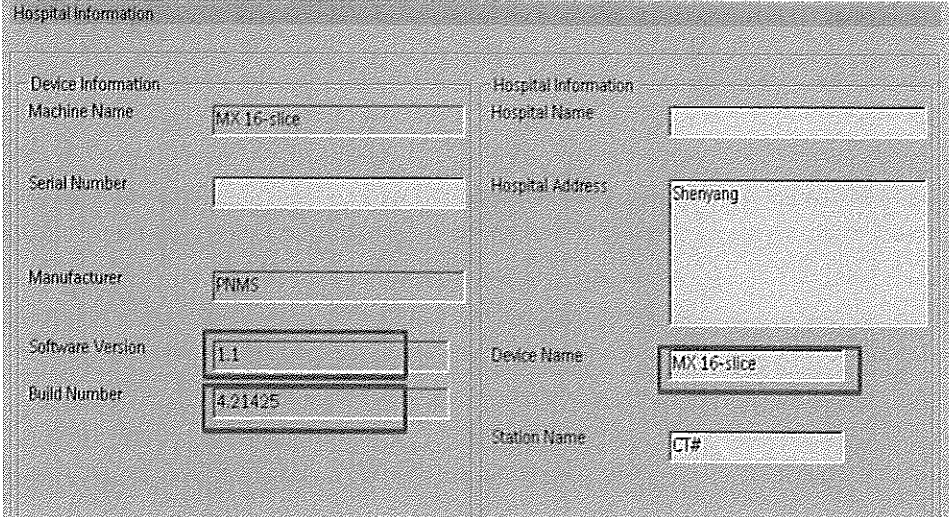
***Software upgrade from v1.1.4.21425 to v1.1.4.21428 to correct software issues on v1.1.4.21425***

<b>AFFECTED PRODUCTS</b>	Philips MX 16-slice CT Systems with software version 1.1.4.21425
<b>PROBLEM DESCRIPTION</b>	<p>The following issues have been found in MX 16-slice systems with software version 1.1.4.21425:</p> <ol style="list-style-type: none"><li>1. The label orientation is displayed incorrectly when "Scanner direction display" is enabled, and the patient position is HFDL (Head First Decubitus Left), HFDR (Head First Decubitus Right), FFDL (Foot First Decubitus Left) or FFDR (Foot First Decubitus Right). The patient position orientation and label text is not consistent. "L" and "R" of scan images are reversed and not consistent with the patient's actual position.</li><li>2. When a survview which is longer than 557mm is stopped by using the Pause button during the scan process, the position of the scan box in survview image is not correct.</li><li>3. For dual survview, if the user uses the Pause button during the second survview, then the position of the scan box in the second survview will not be consistent to the first survview.</li><li>4. For dental applications, when a patient scan is taken with a Gantry tilt, and the tilt angle falls in the range from 1 to -1 degree (not including 0 degree position), the data post-processing on scanner console may not operate normally and the images may not be displayed.</li><li>5. During the filming operation on MX16-slice console software, the clipboard used for copying and pasting images is not cleared between patients. If the operator fails to copy the current patient's images before pasting, a previous patient's images may be present in the clipboard and be copied onto the film of the current patient.</li><li>6. During the Bolus Tracking scan, if the Auto Voice in Tracker scan is enabled, the Tracker scan will be aborted unexpectedly and the diagnostic scan after the tracker scan needs to be manually started.</li><li>7. If the scan protocol with SAS (Spiral Auto Start) function is selected to plan the scan, the SAS option may not be displayed on the Contrast tab of the scan protocol parameter area or the SAS option is displayed but not enabled as pre-configured in the protocol. This issue only occurs on the first helical scan after system startup that applies SAS function. (The issue will not occur on the following scan if any helical scan has been executed after system startup.)</li></ol>

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<b>HAZARD INVOLVED</b>	<p>Issue 1) Potential misdiagnosis or incorrect anatomy classification leading to unnecessary treatment/procedure.</p> <p>Issue 2) Scan on wrong body position leading to rescan of patient.</p> <p>Issue 3) Scan on wrong body position leading to rescan of patient.</p> <p>Issue 4) Dental images cannot be post-processed, which may lead to rescan of patient.</p> <p>Issue 5) Potential misdiagnosis due to mixed patient images, which may lead to unnecessary treatment/procedure.</p> <p>Issue 6) Potential rescan of patient when tracker scan is aborted and the following diagnostic scan is not manually started.</p> <p>Issue 7) Invalid SAS scan due to SAS option is not enabled as expected, which may lead to rescan of patient.</p>
<b>HOW TO IDENTIFY AFFECTED PRODUCTS</b>	<p>All the MX-16 Slice Systems with software version 1.1.4.21425 will be affected. User can navigate to "Processing"→ "Service"→ "System Setting" → "Hospital Information" to find the device information. Check whether the Device Name is "MX 16-slice", Software Version is 1.1 and the Build Number is 4.21425 (see Figure 1).</p> <p>Figure 1: Check Device Name and Software Version</p> 

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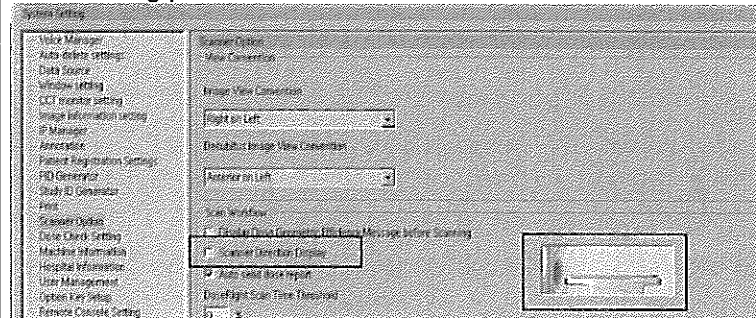
#### ACTION TO BE TAKEN BY CUSTOMER / USER

Until the software is upgraded to v1.1.4.21428, follow the directions below to avoid the issues described in the FSN.

##### Issue 1:

Do not use "Scanner direction display": Open system setting and go to "Scanner Option". If "Scanner Direction Display" option is enabled, cancel (disable) this option.

Note: After the disabling of "Scanner direction display" function, the icon for the patient position in register and protocol select interface will be set as default. This will not affect the scanning process.



##### Issue 2:

If a survview is over 557mm in length, do not use the "Pause button" during survview scan.

##### Issue 3:

Do not use Pause button during dual survview scan.

##### Issue 4:

Do not tilt gantry to the angle between 1 to -1 degree (not including 0 degree) when a patient scan is taken with Gantry tilted. If gantry is tilted to the angle between 1 to -1 degree (not including 0 degree), process the images on EBW for post-processing.

##### Issue 5:

When the copy and paste operation is used to edit patients' films, ensure the patient image is copied from the current patient before pasting to the film. Check the patient information on the image and ensure the desired images are copied onto the film.

##### Issue 6:

When performing a Bolus Tracking scan, do not use the Auto Voice option in Tracker scan. Use the intercom to give breathing instructions to the patient during Bolus Tracking scan.

##### Issue 7:

If the SAS option is displayed on the Contrast tab of the scan protocol parameter area but is not enabled, enable the SAS option manually. If the SAS option is not displayed, select another series and then select back to the series of Helical scan. The SAS option will be displayed and then the clinician can enable the SAS option manually.

This issue can also be avoided if the clinician arranges the first helical scan after system startup without SAS function.

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<b>ACTIONS PLANNED BY PHILIPS</b>	<p>Philips will release Field Change Order (FCO) 72800616 to upgrade the software free of charge.</p> <p>A Philips Field Engineer will contact you to schedule this correction.</p>
<b>FURTHER INFORMATION AND SUPPORT</b>	<p>If you need any further information or support concerning this issue, please contact your local Philips representative:</p> <p>&lt;Philips representative contact details to be completed by the KM / country&gt;</p>